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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,848	11/29/2001	Howard J. Federoff	12610-011001 / 6-11406-97	4642

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EXAMINER	
LIETO, LOUIS D	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/997,848	FEDEROFF ET AL.	
	Examiner	Art Unit	
	Louis D. Lieto	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) *1-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/19/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to the Restriction was received on 1/05/2005. Claims 1-55 are pending in the instant application. Applicant's election without traverse of claims 53-55 of group II drawn to methods of treatment and the species of: 1) the HSV-1 viron host shutoff protein; 2) herpes simplex virus; and 3) a type of protein, which is an immunomodulatory protein in the reply filed on 1/05/2005 is acknowledged. It is noted that the claims were only examined to the extent that they read on the elected invention.

Claims 1-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/05/2005.

Claims 53-55 are currently under examination.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Claim Objections

Claims 53-55 are objected to because of the following informalities: The claims are objected to as being dependent upon withdrawn base claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 53 and 54 are rejected under 35 U.S.C. 1 12, second paragraph as being indefnite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1, 4, 23, and 38 recite the limitations "immunomodulatory proteins". Claims 2-3, 5-22, 24-37, and 39-40 depend on these claims. The word "immunomodulatory" is vague and indefinite as it is unclear what kind of effect on the immune response the protein can mediate. The word "immunomodulatory" is further confusing in the context of the claims as the claims are ultimately directed to the induction of protective immune responses against a tumor, whereas the "immunomodulatory" protein would appear to encompass proteins which could in fact down regulate, suppress, or tolerize immune responses. The metes and bounds of the claimed inventions are not clear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The claims encompass administering to a patient an HSV amplicon encoding an immunomodulatory protein, wherein the HSV amplicon may further encode an antigen protein, or administering a cell comprising an HSV amplicon encoding an immunomodulatory protein, wherein the HSV amplicon may further encode an antigen protein.

Claim 53 is rejected under 35 U.S.C. 102(b) as being anticipated by Pestka et al. (WO 97/00085).

Pestka et al. (WO 97/00085, published 3 January 1997) discloses viral vector systems, for the treatment of tumor cells (Abstract). Herpes virus vectors are contemplated as a vector, and the following immunostimulatory molecules are specifically contemplated: IL-2, IL-12, B7-1, ICAM-1 and GMCSF (Abstract). Pestka et al. discloses using the viral vectors comprising immunostimulating molecules to transduce tumor cells (Abstract). Wherein the viral vector is a HSV vector, which is preferably replication deficient (pg. 21, lines 15-25). Specifically, Pestka et al. teaches by incorporating a reference to a defective HSV vector that offer unique advantages over other systems. Wherein the vector genome consists of multiple copies of a plasmid-based amplicon, with a human cytomegalovirus promoter and lacZ gene as a reporter (pg. 21, lines 25-30; see the reference to Kaplitt et al.). Pestka et al. provides guidance on a packaging cell system comprising an HSV packaging vector that is replication deficient and a plasmid that comprises a functional packaging site and origin of replication (pg. 21, lines 25-30; see the reference to Kaplitt et al.). Therefore, the disclosure of Pestka et al meets the limitations of the above rejected claims.

Claim 54 is rejected under 35 U.S.C. 102(b) as being anticipated by Karpoff et al. (Karpoff et al. Journal of Clinical Investigation (February 1997) Vol. 99, No. 4, pages 799-804).

Karpoff et al. provides guidance on a tumor vaccine consisting of hepatoma cells infected ex vivo with a herpes simplex amplicon that expresses IL-2 or GM-CSF (Abstract). Wherein the HSV amplicon vector is replication deficient (pg. 799, col.2) and the IL-2 or GM-CSF genes were directly cloned into HSVprPUC (pg. 800, col 1). Further, Karpoff et al. teaches using a packaging cell system comprising an HSV packaging vector that is replication deficient and a plasmid that comprises a functional packaging site and origin of replication (pg. 800, col 1; citing to reference 13). Finally, Karpoff et al. teaches administering these cells to rats to treat tumor nodules. (Abstract). Therefore, Karpoff et al. anticipates the claimed invention.

Claims 53 and 54 are rejected under 35 U.S.C. 1O2(e) over U.S. Patent No. 6,344,445, issued on 2/5/02 with a priority date of 10/18/1996, hereafter referred to as Boursnell et al.

Boursnell et al. teaches methods of transducing tumor cells, including hematopoietic tumors, with HSV vectors encoding an immunomodulatory protein (Boursnell et al, columns 39-40, claims 1-16). Boursnell et al. further teaches that the immunomodulatory proteins include IL-1, IL-2, IL-12, GM-CSF, ICAM, RANTES, and B7 (Boursnell et al., columns 2, 7-8, and 40, claim 12). Boursnell et al. also teaches that the transduction of the cells with more than one immunomodulatory protein, such as the transduction of cells with two cytokines or with cytokines and costimulatory molecules, or with any combination of the recited immunomodulatory proteins (Boursnell et al., column 7-8). Further, Boursnell et al. teaches that it was well within the skill of the ordinary artisan at the time of filing to make recombinant vectors, including herpes vectors, that encode more than one immunomodulatory gene, such as an antigen and a cytokine (Boursnell et al., columns 2-3, bridging paragraph).

In regards to the HSV vector, Boursnell et al. specifically teaches the use of HSV amplicons to transduce the cells (Boursnell et al., column 14, lines 17-41). Boursnell et al. provides substantial direction for making mixtures of recombinant HSV amplicons and packaged HSV vectors which encode an immunomodulatory or therapeutic gene; including a packaging cell system comprising an HSV packaging vector that is replication deficient and a plasmid that comprises a functional packaging site and origin of replication (Boursnell et al., column 14, lines 17-41, columns 16-23, Figures 1-6, and column 39-40). While it is noted that Boursnell suggests the packaging of the disclosed amplicons prior to transduction, the applicant's claims are broad and do not limit the way in which the amplicons are transduced into the target cells. Finally, Boursnell et al. teaches that the cells can be transduced in vivo, or ex vivo, and further wherein the cells transduced ex vivo are reintroduced into the patient (Boursnell et al., column 13, lines 24-50). Thus, by teaching all the limitations of the applicant's instant claims, Boursnell et al. anticipates the invention as claimed.

Claims 53 and 54 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S Patent No. 6,051,428, issued on 5/18/2000, with a priority date of 3/21/1997, hereafter referred to as Fong[1] et al.

U.S Patent No. 6,051,428 shares a common assignee with the instant application, specifically the University of Rochester, but has an additional different assignee than the instant application, specifically Sloan-Kettering Institute for Cancer Research. Further, U.S Patent No. 6,051,428 shares common inventorship with Howard Federoff and Joseph Rosenblatt, but was also co-invented by Yuman Fong, who is not listed as a co-inventor of the instant application.

Fong[1] et al. provides guidance on a method for inducing a protective immune response to tumor cells in a patient comprising the step of transducing the tumor cells with a herpes simplex virus amplicon comprising an immunomodulatory protein gene, or transducing the tumor cells ex vivo and introducing the cells into the patient (Claims 19 and 20). Therefore, Fong[1] et al. anticipates the claimed invention.

Claims 53 and 54 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S Patent Application No. 2004/0047837, published on 3/11/2004, with a priority date of 3/21/1997, hereafter referred to as Fong[2] et al.

U.S Patent Application No. 2004/0047837 shares a common assignee with the instant application, specifically the University of Rochester, but has an additional different assignee than the instant application, specifically Sloan-Kettering Institute for Cancer Research. Further, U.S Patent No. 6,051,428 shares common inventorship with Howard Federoff and Joseph Rosenblatt, but was also co-invented by Yuman Fong, who is not listed as a co-inventor of the instant application.

Fong[2] et al. provides guidance on a method for inducing a protective immune response to tumor cells in a patient comprising the step of transducing the tumor cells with a herpes simplex virus amplicon comprising an immunomodulatory protein gene, or transducing the tumor cells ex vivo and introducing the cells into the patient (Claims 19 and 20). Therefore, Fong[2] et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The claims encompass administering to a patient an HSV amplicon encoding an immunomodulatory protein, wherein the HSV amplicon may further encode an antigen protein, or administering a cell comprising an HSV amplicon encoding an immunomodulatory protein, wherein the HSV amplicon may further encode an antigen protein.

Claims 53 and 54 are rejected under 35 U.S.C. 103(a) as being obvious over U.S Patent No. 6,051,428, issued on 5/18/2000, with a priority date of 3/21/1997, hereafter referred to as Fong[1] et al.

The applied reference has a common inventor and one of two assignees with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a

terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

U.S Patent No. 6,051,428 shares a common assignee with the instant application, specifically the University of Rochester, but has an additional different assignee than the instant application, specifically Sloan-Kettering Institute for Cancer Research. Further, U.S Patent No. 6,051,428 shares common inventorship with Howard Federoff and Joseph Rosenblatt, but was also co-invented by Yuman Fong, who is not listed as a co-inventor of the instant application.

Fong[1] et al. provides guidance on a method for inducing a protective immune response to tumor cells in a patient comprising the step of transducing the tumor cells with a herpes simplex virus amplicon comprising an immunomodulatory protein gene, or transducing the tumor cells ex vivo and introducing the cells into the patient (Claims 19 and 20). It is noted that any modifications/changes not taught by Fong[1] et al. are minor and would have been obvious to an artisan. For example, Fong[1] et al. does not specifically claim a method of prophylacticly treating a patient with an HSV amplicon or cells treated *ex vivo* with an HSV amplicon.

It would have been *prima facie* obvious at the time of the claimed invention to modify the teachings of Fong[1] et al. by transducing tumor cells in the patient or *ex vivo* with an HSV amplicon.

One of ordinary skill in the ad would have been motivated by the teachings of Fong[1] et al. prophylacticly treat a patient with an HSV amplicon or cells treated *ex vivo* with an HSV in order

to prevent to vaccinate against cancer.

The person of ordinary skill in the art would have had a reasonable chance of success since Fong[1] et al. provides guidance on a HSV amplicon that can be used to treat cancer, and the administering the HSV amplicon is a minor modification that would have been routine in the art at the time of filing.

Claims 53 and 54 are rejected under 35 U.S.C. 103(a) as being obvious over U.S Patent Application No. 2004/0047837, published on 3/11/2004, with a priority date of 3/21/1997, hereafter referred to as Fong[2] et al.

The applied reference has a common inventor and one of two assignees with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the

same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

U.S Patent Application No. 2004/0047837 shares a common assignee with the instant application, specifically the University of Rochester, but has an additional different assignee than the instant application, specifically Sloan-Kettering Institute for Cancer Research. Further, U.S Patent No. 6,051,428 shares common inventorship with Howard Federoff and Joseph Rosenblatt, but was also co-invented by Yuman Fong, who is not listed as a co-inventor of the instant application.

Fong[2] et al. provides guidance on a method for inducing a protective immune response to tumor cells in a patient comprising the step of transducing the tumor cells with a herpes simplex virus amplicon comprising an immunomodulatory protein gene, or transducing the tumor cells ex vivo and introducing the cells into the patient (Claims 19 and 20).

It is noted that any modifications/changes not taught by Fong[2] et al. are minor and would have been obvious to an artisan. For example, Fong[2] et al. does not specifically claim a method of prophylacticly treating a patient with an HSV amplicon or cells treated *ex vivo* with an HSV amplicon.

It would have been *prima facie* obvious at the time of the claimed invention to modify the teachings of Fong[2] et al. by transducing tumor cells in the patient or *ex vivo* with an HSV amplicon.

One of ordinary skill in the ad would have been motivated by the teachings of Fong[2] et al. prophylacticly treat a patient with an HSV amplicon or cells treated *ex vivo* with an HSV in order to prevent to vaccinate against cancer.

The person of ordinary skill in the art would have had a reasonable chance of success since Fong[2] et al. provides guidance on a HSV amplicon that can be used to treat cancer, and the administering the HSV amplicon is a minor modification that would have been routine in the art at the time of filing.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,344,445, 2/5/02, hereafter referred to as Boursnell et al in view of Chow et al. {Chow et al. (1997) J. Virology. 71 :169-178}.

Boursnell et al. teaches methods of transducing tumor cells, including hematopoietic tumors, with HSV vectors encoding an immunomodulatory protein (Boursnell et al, columns 39-40, claims 1-16). Boursnell et al. further teaches that the immunomodulatory proteins include IL-1, IL-2, IL-12, GM-CSF, ICAM, RANTES, and B7 (Boursnell et al., columns 2, 7-8, and 40, claim 12). Boursnell et al. also teaches that the transduction of the cells with more than one immunomodulatory protein, such as the transduction of cells with two cytokines or with cytokines and costimulatory molecules, or with any combination of the recited immunomodulatory proteins (Boursnell et al., column 7-8). Further, Boursnell et al. teaches that it was well within the skill of the ordinary artisan at the time of filing to make recombinant vectors, including herpes vectors, that encode more than one immunomodulatory gene, such as an antigen and a cytokine (Boursnell et al., columns 2-3, bridging paragraph).

In regards to the HSV vector, Boursnell et al. specifically teaches the use of HSV amplicons to transduce the cells (Boursnell et al., column 14, lines 17-41). Boursnell et al. provides substantial direction for making mixtures of recombinant HSV amplicons and packaged

HSV vectors which encode an immunomodulatory or therapeutic gene; including a packaging cell system comprising an HSV packaging vector that is replication deficient and a plasmid that comprises a functional packaging site and origin of replication (Boursnell et al., column 14, lines 17-41, columns 16-23, Figures 1-6, and column 39-40). While it is noted that Boursnell suggests the packaging of the disclosed amplicons prior to transduction, the applicant's claims are broad and do not limit the way in which the amplicons are transduced into the target cells. Further, Boursnell et al. teaches that the cells can be transduced in vivo, or ex vivo, and further wherein the cells transduced ex vivo are reintroduced into the patient (Boursnell et al., column 13, lines 24-50). Finally, Boursnell et al. teaches that the HSV vector is useful as a rapid and efficient vector for gene transfer of sequences encoding immunogens as a vaccine (Col. 4). Boursnell et al. does not teach where the vector further comprises a sequence encoding the antigen of an infectious agent

Chow et al. supplements the guidance of Boursnel et al. by teaching a Hepatitis DNA vaccine comprising a plasmid that encodes either an IL-2/hepatitis envelope fusion protein, or a bi-cistronic vector that separately encodes both IL-2 and a hepatitis envelope protein (Abstract, Materials and Methods, pg. 170). Further, Chow et al. teaches that the efficacy of a DNA vaccine is greatly improved by the simultaneous expression of IL-2 with the antigen (Abstract).

It would have been *prima facie* obvious at the time of the claimed invention to modify the HSV vector taught by Boursnell et al. to encode both IL-2 and the hepatitis envelope protein taught by Chow et al.

One of ordinary skill in the ad would have been motivated by the teachings ' in both documents to vaccinate an individual with an HSV vector that encoded both IL-2 and the

hepatitis envelope protein because Boursnell et al. teaches that a HSV vector, which encodes both a cytokine and an antigen, is a rapid and efficient means of gene transfer and Chow et al. teaches that the co –expression of IL-2 and the hepatitis envelope protein produces a more effective vaccine.

The person of ordinary skill in the art would have had a reasonable chance of success since Boursnell et al. provides guidance on a HSV vector that co-expresses two proteins. It would comprise a minor modification to the vector to replace the sequence encoding an antigen with one encoding an antigen from a specific infectious agent, and would have been routine in the art at the time of filing.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 53 and 54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19 and 20 of U.S. Patent No. 6,051,428. Although the conflicting claims are not identical, they are not patentably distinct from each other

because claims 19 and 20 encompass a method for inducing a protective immune response to tumor cells in a patient comprising the step of transducing the tumor cells with a herpes simplex virus amplicon comprising an immunomodulatory protein gene, or transducing the tumor cells ex vivo and introducing the cells into the patient (Claims 19 and 20). Thus claims 19 and 20 are drawn to the same claimed invention as claims 53 and 54.

Claims 53 and 54 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19 and 20 of copending Application No. 2004/0047837. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 19 and 20 encompass a method for inducing a protective immune response to tumor cells in a patient comprising the step of transducing the tumor cells with a herpes simplex virus amplicon comprising an immunomodulatory protein gene, or transducing the tumor cells ex vivo and introducing the cells into the patient (Claims 19 and 20). Thus claims 19 and 20 are drawn to the same claimed invention as claims 53 and 54.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claims allowed.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571)-272-0735. Information

regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Dr. Louis D. Lieto
Patent Examiner
Art Unit 1632

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER